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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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The Dow Chemical Company			HELM, CARALYNNE E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/785,327	Applicant(s) SHESKEY ET AL.
	Examiner CARALYNNE HELM	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 May 2011.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 21-28 is/are pending in the application.
- 5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 21-28 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08) _____
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 17, 2011 has been entered.

Election/Restrictions

To summarize the election of record, applicant elected Group I drawn to processes for dispersing fluids in a mass of solid powder particles.

Applicant is advised that should claim 27 be found allowable, claim 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 28 recite that the binder is present "to encourage agglomeration". This is an intended use that does not require the formation of agglomerates as its result. Therefore it is not clear if agglomerates must be made by the recited method steps. As a result the later recitation of the properties of "agglomerated particles" in line 6 of claim 21 and line 7 of claim 28 lacks proper antecedent basis.

Claims 22-27 depend from claim 21 but do not clarify these issues, therefore these claims are also indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie-Muncy et al. (previously cited) in view of Richardson et al. (previously cited) as evidenced by Chevillard et al. (Colloid and Polymer Science 1997 275:537-545).

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by whipping a coating medium into a foam then applying the foam to this powder so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11). In particular, they teach that a binding agent is included at 0.1 to 20% in water to make up the foam composition (see column 2 lines 33-35; instant

claim 26). Methyl cellulose in combination with a hydrophilic gelatinous substance, where gelatin is a desired variety in the latter category, is taught (see claims 4 and 5). Methyl cellulose can be categorized as a surfactant, therefore this combination yields a surfactant combined with a binder (see Chevillard et al. page 537 column 1). Further, Hardie-Muncy et al. teach that their process forms a foam by whipping air into the coating composition (water based air foam comprising surfactant in the presence of a binder) then mixes in the powder to form agglomerates without atomizing the foam (see column 2 lines 46-57; instant claims 22 and 28). Hardie-Muncy et al. do not explicitly teach that the powder particles contain therapeutic or recite their size.

Richardson et al. teach hygroscopic (moisture sensitive and slightly water soluble) bioactive (therapeutic) components (see column 1 lines 7-11). These components are taught to be less than 1000 microns in diameter (see (column 8 lines 35-41; instant claim 21).

In light of the teachings of Hardie-Muncy et al. to combine agents they teach as binders, it would have been obvious to one of ordinary skill in the art at the time of the invention to select methyl cellulose and gelatin as a binder combination based upon their direction in the claims. Since some bioactive powders are known to be sized less than 1000 microns and also to be moisture sensitive and slightly water soluble, based on Richardson et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to use such powders in the process taught by Hardie-Muncy et al. to protect them from undesired moisture and help them retain their desired structure and function. This process would encourage the agglomeration of the powder rather

than uniform coating since agglomeration is the specified purpose of the method of Hardie-Muncy et al. In addition, these agglomerated particles/powder are capable of being pressed into a tablet without any coating steps due to their agglomerated structure already including a binder (see instant claim 21). Therefore claims 21-22 and 26 are obvious over Hardie-Muncy et al. in view of Richardson et al. as evidenced by Chevillard et al.

Claims 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardie-Muncy et al. as evidenced by Parsley reference (previously cited) and the Particle Size reference (previously cited) as evidenced by Chevillard et al.

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by foaming a coating medium then applying the foam to this powder so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11; instant claim 21). In one example, a water based air foam is produced utilizing gelatin as a binding agent (binder) in water and combined, without atomization, with a collection of bread powder particles (see column 2 lines 28-33 and example 1; instant claim 22). One subset of these powder particles (small bread particles) is taught to pass through a 14 US sieve size and be retained on a 50 US sieve size. The Particle Size reference teaches that a 14 US sieve size has openings that are 1.41mm in diameter while a 50 US sieve size has openings that are 297 μm in diameter. Thus this subset of powder particles must be between 297 and 1410 μm . The binding agent is included at 6.2% in the foam (as calculated by the examiner – see instant claim 26). In

addition, parsley, a water insoluble or slight water soluble material, is included as a powdered particulate ingredient in the agglomerate preparation. The Parsley reference teaches that this plant is known to have medicinal effects (e.g. therapeutic agent) (see paragraph 7; instant claim 21). Methyl cellulose in combination with a hydrophilic gelatinous substance, where gelatin is a desired variety in the latter category, is taught (see claims 4 and 5). Methyl cellulose can be categorized as a surfactant, therefore this combination yields a surfactant combined with a binder (see Chevillard et al. page 537 column 1). Hardie-Muncy et al. do not explicitly exemplify a method with a combination of methyl cellulose and gelatin as the binder.

In light of the teachings of Hardie-Muncy et al. to combine agents they teach as binders, it would have been obvious to one of ordinary skill in the art at the time of the invention to select methyl cellulose and gelatin as a binder combination based upon their direction in the claims. The selection of any order of adding ingredients is *prima facie* obvious in the absence of new or unexpected results (see MPEP2144.04 IVc). Therefore the addition the powder particles on top of the foam or vice versa is obvious from the teachings of Hardie-Muncy et al. since no evidence is provided by the instant application of any unexpected result from one particular order of addition (see instant claims 23 and 27-28). This process would encourage the agglomeration of the powder particles rather than uniform coating since agglomeration is the specified purpose of the method of Hardie-Muncy et al. Also, it would have been obvious to one of ordinary skill in the art to include a set of powder particles whose average size was less than 1000 μm , 750 μm or 500 μm as feed material for the agglomerates as a matter of routine

experimentation given that the lower end of the acceptable size range for the small bread powder particles is 297 μm (see instant claims 21 and 24-25). In addition, the agglomerated powder particles are capable of being pressed into a tablet without any coating steps due to their agglomerated structure already including a binder (see instant claim 21). Therefore claims 21-28 are obvious over Hardie-Muncy et al. as evidenced by the Parsley reference and the Particle Size reference and Chevillard et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-23 and 26-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,070,828 (hereafter patent '828') in view of Hardie-Muncy et al. as evidenced by

Rudnic et al. (previously cited) and Chevillard et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where powder particles are contacted with water-based air foam and then mixed. Aqueous liquid diluent is present at a proportion that meets the limitation of 99.99 to 90 weight percent. While the powder particle size recited by patent '828 is 1 mm to 25 mm and that of the instant claim is less than 1000 microns, routine experimentation by one of ordinary skill in the art based upon the teachings of patent '828 would render this limitation obvious. Patent '828 teaches cellulose ethers and poly(vinylpyrrolidone) in combination as the polymer included in the foam. Poly(vinyl pyrrolidone) is a known binder in the pharmaceutical art and meets the limitation of the instantly claimed binder (see Rudnic et al. claim 8). These claims of patent '828 are silent regarding the atomization of the foam, the solubility of the drug powder particles, whether the foam is applied on top of the powder particles and a cellulose ether that is a surfactant.

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by whipping a coating medium into a foam then applying the foam to the (on top of without atomization) powder particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11). This process coats the powder particles, as desired by patent '828. In addition, they also teach methyl cellulose as a binding hydrophilic polymer in the coating medium (see claim 4). Methyl cellulose can be categorized as a surfactant (see Chevillard et al. page 537 column 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to select methyl cellulose as the cellulose ether in the foam as the simple substitution of one known element for another to yield a predictable result. Its combination with the binder poly(vinyl pyrrolidone) then yields the method where the water-based air foam comprising a surfactant is mixed with a powder in the presence of a binder. The encouragement of agglomeration of the powder particles rather than uniform coating of the powder particles is a necessary by-product of the binder and process steps. In addition, it also would have been obvious to apply the water-based air foam of patent '828 on top of their claimed powder particles without atomization since Hardie-Muncy et al. teach this application procedure as known means for the contacting/coating of powder particles with a water-based air foam. Further it would have been obvious to select drug powder particles that are water-insoluble or only slightly soluble in water so as to avoid dissolution in the foam medium. Given that the components and steps are the same in both the instant method and that of claims 1-2 of U.S. Patent No. 7,070,828 in view of Hardie-Muncy et al. as evidenced by Rudnic et al. and Chevillard et al., the result in both instances must be the same agglomerated powder particles. Therefore claims 21-23 and 26-28 are obvious over claims 1-2 of U.S. Patent No. 7,070,828 in view of Hardie-Muncy et al. as evidenced by Rudnic et al. and Chevillard et al.

Claims 21-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,070,828

(hereafter patent '828') in view of Hardie-Muncy et al. Hagemann et al. (US Patent No. 5,211,957) as evidenced by Rudnic et al. and Chevillard et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where powder particles are contacted with water-based air foam and then mixed. Aqueous liquid diluent is present at a proportion that meets the limitation of 99.99 to 90 weight percent. Patent '828 teaches cellulose ethers and poly(vinylpyrrolidone) in combination as the polymer included in the foam. Poly(vinyl pyrrolidone) is a known binder in the pharmaceutical art and meets the limitation of the instantly claimed binder (see Rudnic et al. claim 8). The claim of patent '828 is silent regarding the atomization of the foam, the solubility or size of the drug powder particles, whether the foam is applied on top of the powder particles and a cellulose ether that is a surfactant.

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by whipping a coating medium into a foam then applying the foam to the (on top of without atomization) powder particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11). In addition, they also teach methyl cellulose as a binding hydrophilic polymer in the coating medium (see claim 4). This process coats the powder particles as desired by patent '828 Methyl cellulose can be categorized as a surfactant (see Chevillard et al. page 537 column 1).

Hagemann et al. teach microparticles of the slightly water soluble drug diclofenac that are sized at less than 200 μm (see column 2 lines 21-25). The microparticles are

coated with a composition that includes poly(vinyl pyrrolidone) and lower alkyl ethers of cellulose, which include methyl cellulose (see claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to select methyl cellulose as the cellulose ether in the foam as the simple substitution of one known element for another to yield a predictable result. Its combination with the binder poly(vinyl pyrrolidone) then yields the method where the water-based air foam comprising a surfactant is mixed with a powder in the presence of a binder. The encouragement of agglomeration of the powder particles rather than uniform coating the powder particles is a necessary by-product of the binder and process steps. The selection of drug powder particles as taught by Hagemann et al. also would have been obvious since it is desired that they are coated with the same material taught in the foam material that ultimately coats the powder particles of patent '828. In addition, it also would have been obvious to apply the water-based air foam of patent '828 on top of their claimed powder particles without atomization since Hardie-Muncy et al. teach this application procedure as known means for the contacting/coating of powder particles with a water-based air foam. The selection of any order of adding ingredients is *prima facie* obvious in the absence of new or unexpected results (see MPEP2144.04 IVc). Therefore the addition the powder particles on top of the foam or vice versa is obvious from the teachings of Hardie-Muncy et al. since no evidence is provided by the instant application of any unexpected result from one particular order of addition. Given that the components and steps are the same in both the instant method and that of claims 1-2 of U.S. Patent No. 7,070,828 in view of

Hardie-Muncy et al. as evidenced by Rudnic et al. and Chevillard et al., the result in both instances must be the same agglomerated powder particles. Therefore claims 21-28 are obvious over claims 1-2 of U.S. Patent No. 7,070,828 in view of Hardie-Muncy et al. and Hagemann et al. as evidenced by Rudnic et al. and Chevillard et al.

Claims 21-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 10-11 of U.S. Patent No. 7,011,702 (hereafter patent '702) in view of Hardie-Muncy et al. and Baichwal et al. (previously cited) as evidenced by Chevillard et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a method where powder particles are agglomerated by being contacted with water-based air foam and then mixed. Aqueous liquid diluent is present at a proportion that meets the limitation of 99.99 to 90 weight percent. In addition, methyl cellulose is taught in the aqueous air foam. The particle size, presence of a therapeutic, and presence of a binder are not recited by the claims of patent '702. Further, the patented claims are silent regarding the atomization of the foam and whether it is applied on top of the powder particles.

Agglomerated powder particles containing a medicament are taught by Baichwal et al. (see claim 1). In addition, the powder particles utilized in these agglomerates are taught to be 10 μm or less (see column 11 lines 28-48).

Hardie-Muncy et al. teach the agglomeration of moisture sensitive particulate materials by whipping a coating medium into a foam then applying the foam to the (on

top of without atomization) powder particles so as to agglomerate and protect them from exposure to moisture (see abstract and column 1 lines 5-11). Methyl cellulose in combination with a hydrophilic gelatinous substance, where gelatin is a desired variety in the latter category, is taught a binding mixture in the coating medium (see claims 4 and 5). Methyl cellulose can be categorized as a surfactant, therefore this combination yields a surfactant combined with a binder (see Chevillard et al. page 537 column 1). Further, Hardie-Muncy et al. teach that their process forms a foam by whipping air into the coating composition (water based air foam comprising surfactant in the presence of a binder) then mixes in the powder particles to form agglomerates without atomizing the foam (see column 2 lines 46-57).

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the powder particles of Baichwal et al. in the method of patent '702 since both envisioned the production of an agglomerated final product. It further would have been obvious to select a combination of gelatin and methyl cellulose for addition to the foam since this combination was known to be useful in generating a water base air foam for agglomerating powder particles. In addition, it also would have been obvious to apply the water-based air foam of patent '828 on top of their claimed powder particles without atomization since Hardie-Muncy et al. teach this application procedure as known means for the contacting/coating of powder particles with a water-based air foam. The selection of any order of adding ingredients is *prima facie* obvious in the absence of new or unexpected results (see MPEP2144.04 IVc). Therefore the addition the powder particles on top of the foam or vice versa is obvious from the teachings of

Hardie-Muncy et al. since no evidence is provided by the instant application of any unexpected result from one particular order of addition. This process would encourage the agglomeration of the powder particles rather than uniform coating since agglomeration is the specified purpose of the method of Hardie-Muncy et al. Further it would have been obvious to select drug powder particles that are water-insoluble or only slightly soluble in water so as to avoid dissolution in the foam medium. Therefore claims 21-28 are obvious over claims 8 and 10-11 of U.S. Patent No. 7,011,702 in view of Hardie-Muncy et al. and Baichwal et al. as evidenced by Chevillard et al.

Response to Arguments

Applicant's remarks filed June 17, 2011 have been fully considered but they are not persuasive and do not point out where the limitations of the amended claims are not met by the prior art.

All previous grounds of rejection are hereby withdrawn in favor of the new grounds of rejection detailed above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634